

K110245

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UTF Stem

510(k) Summary

510(k) Summary of Safety and Effectiveness AUG - 4 2011

Submitted by: United Orthopedic Corporation
Address: No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan
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Date of Summary: July 25, 2011
Contact Person: Fang-Yuan Ho
Manager, Regulatory Affairs
Proprietary Name: UTF Stem
Common Name: Total Hip Prosthesis
Device Classification Hip joint metal/polymer/metal semi-constrained porous-coated
Name and Reference: uncemented prosthesis under 21CFR 888.3358
Device Class Class II
Panel Code Orthopaedics Device
Device Product Code LPH, KWY, LZO
Predicate Device:
1. Smith & Nephew ANTHOLOGY Primary hip system
(K052792)
2. BIOMET TAPERLOC Hip System (K921301, K043537)

Device Description:

UTF Stem is a modular, wedge-shaped stem with 12/14 neck taper, which is made from forging Ti-6Al-4V alloy conforming to ASTM F 620 and the proximal part of each femoral stem is coated with CP Ti plasma spray. The net-shape of stem was forged by the titanium bar (ASTM F136). Circumferential titanium plasma coating sprayed with CP Ti powder (ASTM F1580) provides biological fixation. This device is collarless to



allow for self-seating of the implant between the lateral and medial cortices of the femoral canal. UTF Stem is available with standard offset and high offset options to restore hip biomechanics. Each type of offset is available in 10 sizes ranging.

For total hip replacement, UTF Stem can be used in conjunction with UNITED Femoral Head (K994078, K022520 and K111546), U2 Acetabular Cup Liner (K050262), XPE Cup Liner (K111546), U2 HA/Ti Plasma Spray Cup (K050262), U2 Ti Plasma Spray Cup (K050262) and U2 Ti Porous Coated Cup (K111546). As using with the U2 Acetabular Cup Liner (K050262), UTF Stem can be used with 26 mm and 28 mm Femoral Head (K994078 and K022520) and 28 mm ceramic Femoral Head (K103479). As using with XPE Cup Liner (K111546), UTF Stem can be used with 28 mm, 32 mm and 36 mm metal Femoral Head (K022520, K111546), and 28 mm and 32 mm Ceramic Femoral Head (K103479). Only U2 Ti Porous Coated Cup (K111546) and XPE Cup Liner (K111546) can be used in conjunction with the 32 mm and 36 mm Femoral Head (K111546, K103479). For bipolar hip replacement, UTF Stem also can be used in conjunction with 26 mm, 28 mm, 32mm and 36mm Femoral Head (K994078, K022520, K111546) and Bipolar implants (K050269, K101670). UNITED Femoral Head and Bipolar Cap are made of Co-Cr-Mo alloy, while Ceramic Femoral Head is manufactured from alumina. Acetabular Cup Liner and Bipolar Cap Liner are made of UHMWPE, while U2 Acetabular Cup shells are manufactured from forged Titanium alloy.

Intended Use:

This device is indicated for use in total hip arthroplasty or bipolar arthroplasty undergoing primary and revision surgery for the following conditions:

- Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia



- Inflammatory degenerative joint disease such as rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- Revision procedures where other treatments or devices have failed

UTF Stem is designed for cementless use.

Basis for Substantial Equivalence:

The safety and effectiveness of "UNITED" UTF are substantially equivalent to "BIOMET" TAPERLOC Hip System which was previously cleared under K921301 and K043537 and "Smith & Nephew" ANTHOLOGY Primary hip system which was previously cleared under K052792. The intended use, Morse Taper locking, substrate materials, and sterilization method of "UNITED" UTF Stem are identical to predicate devices, "Smith & Nephew" ANTHOLOGY Primary hip system and "BIOMET" TAPERLOC Hip system. All of these three systems are flat tapered wedge geometry stem with 12/14 neck taper and collarless. Both "UNITED" UTF Stem and "BIOMET" TAPERLOC Hip system are coated with Ti Plasma Spray, while "Smith & Nephew" ANTHOLOGY Primary hip system is coated with HA/Ti Plasma Spray. Both "UNITED" UTF Stem and "Smith & Nephew" ANTHOLOGY Primary hip system have two options, standard offset and high offset, while "BIOMET" TAPERLOC Hip system has standard and Lateralized.

Performance Test – Bench:

This 510(k) was prepared in accordance with "Class II Special Controls Guidance Document- Hip Joint Metal Polymer Constrained Cemented or Uncemented Prosthesis", "Guidance for Non-clinical Information for Femoral Stem Prostheses", "Guidance



Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components", "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems" and "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements". The following mechanical properties of this device have been performed:

- Distal fatigue strength of UTF Stem
- Neck fatigue strength of UTF Stem
- Femoral head disassembly loads for metal femoral head in conjunction with UTF Stem
- Range of motion analysis
- Burst test, fatigue test, burst test for post-fatigue, rotational resistance test and pull-off test for ceramic femoral head with UTF Stem
- Evaluation of microstructure of the modified surface



Food and Drug Administration
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Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

United Orthopedic Corporation
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Manager, Regulatory Affairs
No. 57, Park Avenue 2, Science Park
Hsinchu, 300 Taiwan

AUG - 4 2011

Re: K110245

Trade/Device Name: UTF Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated
uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, KKY, LZO
Dated: July 25, 2011
Received: July 27, 2011

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use

510 (k) Number (if known): _____

Device Name: UTF Stem

Indications for Use:

This device is indicated for use in total hip replacement or bipolar hip replacement undergoing primary and revision surgery for the following conditions: non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia; inflammatory degenerative joint disease such as rheumatoid arthritis; correction of functional deformity; treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; revision procedures where other treatments or devices have failed.

UTF Stem is designed for cementless use.

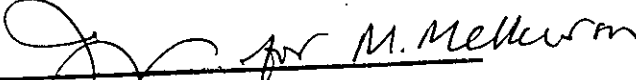
Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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